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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/902,692	07/30/97	REA W	16715CIP

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TODD E ALBANESI
CRUTSINGER & BOOTH
1601 ELM STREET SUITE 1950
THANKSGIVING TOWER
DALLAS TX 75201-4744

EXAMINER	
SCHWADRON, R	
ART UNIT	**PAPER NUMBER**
1644	13

DATE MAILED: 06/18/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
08/902,692	Rea et al.
Examiner	**Group Art Unit**
Ron Schwadron, Ph.D.	1644

☒ Responsive to communication(s) filed on *Apr 9, 1999*.

☒ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *8-19, 21, 32, and 40-59* is/are pending in the application.

Of the above, claim(s) *8-19, 21, 32, and 40-48* is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *49-59* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

1. Claims 49-59 are under consideration. Claims 1-7,20,22-31,33-39 have been cancelled.

RESPONSE TO APPLICANTS ARGUMENTS

2. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because of the following reasons.

A) The instant application needs to claim priority to PCT/US96/01205 under 35 USC 120, not 35 USC 119 (see MPEP section 1895.01, page 1800-131). In addition, the first sentence of the specification indicates that priority is claimed as a CIP which could only be claimed under 35 USC 120.

B) The first paragraph of the specification indicates that priority is claimed to US application 08/380063. There is no priority claim to said application in the instant declaration. Priority to said application would be claimed under 35 USC 120 as a CIP. If applicant does not intend to claim priority to US application 08/380063, then reference to said application needs to be deleted from the first paragraph of the specification (irregardless of whether said application is related to PCT/US96/01205) because reference to said application in the first paragraph of the specification indicates a claim of priority to said application.

C)It does not state that the person making the oath or declaration in a continuation-in-part application filed under the conditions specified in 35 U.S.C. 120 which discloses and claims subject matter in addition to that disclosed in the prior copending application, acknowledges the duty to disclose to the Office all information known to the person to be material to patentability as defined in 37 CFR 1.56 which occurred between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

3. The amendment filed 4/9/99 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows.

A) The abstract constitutes new matter for the reasons elaborated in paragraph 5 of this Office Action.

B) The deletion of the term "normal" or "normal(non-cancerous or otherwise dysfunctional)" from the various passages of the specification indicated in said amendment creates new matter. The particular passages from which the term "normal" is deleted disclose methods for preparing the lysate used in the claimed method wherein the lysate is prepared from an individual's own "normal" cells. The removal of the term "normal" creates a new method of preparing the lysate wherein it is not specified that "normal" lymphocytes from a diseased individual are used. There is no disclosure in the specification as originally filed of the scope of such an invention (eg. it constitutes new matter). Regarding the procedure disclosed in pages 8-10 of the specification, the last paragraph of page 8 indicates that it is practiced with "normal" lymphocytes. Furthermore, assuming arguendo that the last paragraph of page 8 did not recite the use of "normal" lymphocytes, the procedure disclosed in pages 9-10 is drawn to a specific set of experimental procedures which does not provide support for the scope of other methods disclosed in the specification wherein the term "normal" has been removed, wherein said methods do not recite the specific steps recited in pages 9 and 10 of the specification.

Applicant is required to cancel the new matter in the reply to this Office action.

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 49-59 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession

of the claimed invention.

There is no support in the specification as originally filed for the method of claim 49 which does not recite the use of "normal" lymphocytes for the reasons elaborated in paragraph 3 of this Office Action. Regarding the particular steps recited in the method, there is no support in the specification as originally filed for the recitation of step (b) in claim 49. The particular step recited while disclosed in the context of the method disclosed in the specification, pages 9 and 10 is not disclosed in the context of methods which do not recite all of the particular steps disclosed in pages 9 and 10 of the specification. Regarding steps (c) and (d), there is no disclosure in the specification as originally filed of said steps wherein isolated mixed T and B lymphocytes are propagated. There is also no disclosure of said steps in a method for treating a chemically sensitive individual. There is no disclosure in the specification as originally filed of the use of "mixed T and B lymphocytes" in the various procedures recited in claims 51 and 52. There is no support in the specification as originally filed for the recitation of "density gradient technique" in claim 51. The specification does disclose the use of a sodium diatrizoate and polysucrose density gradient technique in the context of the particular steps recited in the specification, pages 9-10. Regarding the various other steps recited in claims 51-59, said steps are not disclosed in the specification in the context of a method for treating chemical sensitivity. There is no support in the specification as originally filed for the scope of the claimed invention (eg. the claimed inventions constitute new matter). There is support in the specification as originally filed for a method of treating chemical sensitivity using the method recited in pages 9 and 10 in specification.

6. Claims 49-59 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 49-59 are indefinite in the recitation of "chemically sensitive individual" because it is unclear what this means or encompasses. It is unclear as to what diseases are encompassed by said term and it appears to have no art recognized meaning. Furthermore, it is also unclear as to whether this term encompasses actual physical maladies versus psychological manifestations in patients that have no real physical ailment (see Barsky et al.). It is unclear what is encompassed by the term "chemically sensitive individual".

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 49-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Youdim et al. in view of Warren (US Patent 4,435,384).

Youdim et al. teach the treatment of "environmentally sensitive patients" with transfer factor (see entire document). The transfer factor is prepared from lysed leukocytes (see page 56, first column). It appears that these "environmentally sensitive patients" would be encompassed by the term "chemically sensitive individual". Youdim et al. do not teach that the transfer factor was produced from autologous blood cells as per claim the claimed invention. Warren teaches that transfer factor can be obtained from the lymphocytes of any individual as long the donor has no history of recurrent infection by herpes virus (see column 2). Therefore a routineer would have used any source of lymphocytes, including autologous, for preparing transfer factor for use in the method taught by Youdim et al. Youdim et al. do not teach that the transfer factor was produced using the particular steps recited in the claimed method. Warren teaches that transfer factor can be produced by a variety of different methods and lists one particular method (see columns 2 and 3). The steps recited in the claimed method are art known procedures that would be expected to yield a lysate containing transfer factor. Regarding the use of "mixed T and B lymphocytes", Warren teaches that transfer factor is produced from lymphocytes (see column 2). The cells used in the method taught by Warren are propagated in that they are cultured in vitro. The use of commercially available density gradients such as FICOLL to separate lymphocytes is well known in the art. Warren teaches the use of heparinized tubes to collect the blood sample. Warren teaches 37 degree incubation of lymphocytes (see column 2). Youdim et al. teaches subcutaneous administration of transfer factor (see page 56, column 2). Youdim et al. teaches multiple administration of transfer factor (see page 56, column 2). Youdim et al. teaches that skin testing (eg. DTH) can be used to measure the response to transfer factor. It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Youdim et al. teach the treatment of "environmentally sensitive

patients" with transfer factor, Warren teaches that transfer factor can be obtained from the lymphocytes of any individual as long as the donor has no history of recurrent infection by herpes virus, and the preparation recited in the claims appears to be transfer factor made by a method that uses art known techniques that would have been obvious to use to prepare transfer factor.

9. No claim is allowed.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Papers should be faxed to Group 1600 at (703) 305-3014.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Ron Schwadron whose telephone number is (703) 308-4680. The examiner can normally be reached Monday through Thursday from 7:30 to 6:00. The examiner can also be reached on alternative Mondays. A message may be left on the examiners voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist

whose telephone number is (703) 308-0196.

RONALD B. SCHWADRON
PRIMARY EXAMINER
GROUP ~~1800~~ 1600

Ron Schwadron, Ph.D.
Primary Examiner
Art Unit 1644
June 17, 1999